THE ISSUE OF FAIRNESS OF THE TRIPS AGREEMENT FOR THE DEVELOPING AND LEAST-DEVELOPED COUNTRIES IN INTERNATIONAL TRADE PRACTICES ON PATENTS OF PHARMACEUTICALS*

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ABSTRACT

This paper is based on research in the area of the intellectual property law and the international trade law. The research examines whether the TRIPS Agreement is fair for the developing and least developed countries (DLDCs), particularly in cases of international trade practices on patents of pharmaceuticals. The research is mainly library research, which is conducted at the Faculty of Law, Monash University, Australia. The completion of this paper is using a number of selected books and international journals, case law, documents of international organization, and international agreement and convention.

Important findings were shown by the research that from the perspective of DLDCs, the TRIPS Agreement is unfair due to several significant factors. It is argued that some fundamental differences between DLDCs and developed countries of their economic and legal enforcement conditions are generated imbalance treatment of the TRIPS Agreement in the two-category countries. Several recommendations are also given to governments and international organization in order to evaluate current system of intellectual property rights protection-international trade interface, and to create greater fairness in the implementation of the TRIPS Agreement.

I. Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has had an immense role on international trade practice. Although the World Trade Organization (WTO) Members (the Members) must accept provisions of TRIPS as part of the agreement,[1] many developing and least-developed countries (DLDCs) were fairly lacking in readiness to adopt TRIPS.[2] Still, the Members have to provide protection in regards to intellectual property rights (IPR) as given in Sections 1 to 7 of TRIPS.

The patent system, which is one of the substances of IPR arranged by TRIPS, is facing intense criticism from DLDCs especially on its

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1 Grubb, Phillip W., *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (Clarendon Press, Oxford, 1999), p31

2 *Ibid.*, p32

provision on pharmaceuticals. Firstly, the system has to provide protection of inventors' exclusive rights and incentives for innovation resulting from research and development (R&D). Next, it has also an obligation to ensure that there is affordable medicine in all societies. This issue is significantly important, as access to health facilities including access to medicine becomes one of human rights issues. However, it is not easy to balance both obligations of TRIPS at multinational levels.

In developed countries, high-tech R&D becomes a priority while there is a competitive market that needs better products from new inventions. Investors put their capital in R&D to make a profit. For developed countries, there are relatively no economic impediments to developing high-cost R&D in practice. Thus, it is easier for developed countries to conform to TRIPS and it is to their advantage to promote protection on IPR and advance R&D.

On the contrary, for DLDCs, TRIPS and the patent system merely creates a burdensome position. Many DLDCs are facing economic crisis. Because of this, DLDCs have found that patented medicines are unaffordable.[3] Because of the 'monopoly' characteristic of the patent system,[4] there has been a relative shortage of access to particular patented medicines, for example HIV/AIDS medicines. Furthermore, there is political pressure from pharmaceutical companies that are mostly based in developed countries for patent protection.

This paper will analyse whether the IPR regime especially TRIPS and the patent systems provide fairness for DLDCs in international trade practices. It focuses on articles in TRIPS related to compulsory licensing and parallel importing for pharmaceuticals. A practical approach will be considered with emphasis on the principle of fairness. Finally, it suggests ways for managing problems faced by DLDCs.

II. Analysis of the Issue of Fairness of TRIPS related to Patents of Pharmaceuticals for DLDCs

There are some tensions between the pharmaceutical companies that seek protection for their investment in R&D and DLDCs, which look for more access and affordable drugs. These tensions are centred around trade and drug access (getting the drug into the market) and IPR, 'public goods and private profit',[5] and finally between compassionate concerns and IPR.

With respect to the question whether TRIPS offers fairness to DLDCs, we can draw on a principle stated by Rawls in *The Law of People*:

> Just as a citizen in a liberal society must respect other persons' comprehensive religious, philosophical, and moral doctrines provided they are in accordance with a reasonable political conception of justice, so a liberal society must respect other societies organized by comprehensive doctrines, provided their political and social institutions meet certain conditions that lead the society to adhere to a reasonable law of peoples.[6]

TRIPS does not respect that principle in that it does not value enough the economic differences between countries. The paper tries

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[3] Das, Bhagirath Lal, *An Inroduction to the WTO Agreements: Trade and Development Issues and the World Trade Organisation* (Zed Books Ltd., London and New York - Third World Network, 1998), p115

[4] Fitzpatrick, Ben, 'Basic Principles of Patent Law', *Patents: the New Frontiers* (Leo Cussen Institute, Legal Professional Development, November 2001), p1.1

[5] Mutume, Gumisai, 'Health and Intellectual Property – Poor Nations and Drug Firms Tussle over WTO Patents Provisions', *Africa Recovery* (2001), 15, 1-2, p14

[6] Rawls, John, 'The Law of Peoples' in *On Human Rights: The Oxford Amnesty Lectures 1993*, ed. Stephen Shute and Susan Hurley (New York Basic Books, 1993), p42-82 quoted by Buchanan, Allen, 'Justice, Legitimacy, and Human Rights' in *The Idea of a Political Liberalism: Essay on Rawls*, ed. Victoria Davion and Clark Wolf (Rowman & Littlefield Publishers, Inc., 2000), p74

to analyse the problem of implementing TRIPS in light of this basic principle and will suggest ways in which TRIPS could be made more equitable.

The question of whether the patent system of TRIPS provides fairness comes up instantly when health and profit are in conflict. A patent gives exclusive privileges and it is equivalent to granting a monopoly to some extent in a market for a certain product.[7] While a patent gives benefit to the holder, there is a need for low-price pharmaceuticals. This will not happen because practically a patent leads to higher prices. Therefore, the two interests are not balanced.

Prior to TRIPS, the absence of patent protection had permitted easy and cheaper access to generic drug equivalents. For many DLDCs, unaffordable prices and shortage of medicine have became a problem particularly since the patent system applied by TRIPS.[8] It is argued that these problems result from the functioning of the patent system especially in pharmaceuticals, which needs reasonably high-cost R&D.[9]

The concept of TRIPS came from strong economy-based countries, which wanted to protect their rights on intellectual property. The desire for protection has increased because of the need for investment in R&D. Further, without investment in R&D, new drugs might not be tested and developed. The pharmaceutical industry, which is a competitive and a high-cost industry,[10] depends on the success of R&D. It creates a certain bargaining power for the investor.[11] So, without encouragement of IPR protection, R&D might not survive. However, R&D is essential for improved health. R&D in pharmaceuticals has made a significant contribution to prevention, cure, management of health care systems, and it increases quality of innovation on new medicines.[12] Unfortunately, DLDCs are not in a situation where IPR and R&D have much priority.

Under TRIPS, while the patent system was seen as a credit given to a person who has invented something novel and it is judged as an incentive to improve the quality of certain field of human life, the Members were given a certain autonomy in regulating their patent laws and were permitted to exclude pharmaceuticals as a subject matter of patents as a measure necessary to protect public health.[13] The Members can provide limited exceptions to the patents by issuing compulsory licensing and parallel importation of protected products.[14] This is supposed to benefit DLDCs.

The Preamble of TRIPS acknowledges the concern of DLDCs and their need for special treatment. It has recognized the particular needs of these countries in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a reliable and feasible technological base.[15] These countries should be able to use flexibility in TRIPS provisions to protect their public health.[16] This flexibility can be read which is covered in Article 31. However, because of

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[7] Fitzpatrick, Ben, *Loc. Cit.*

[8] Ombaka, Eva, 'TRIPS and Pharmaceuticals', *Echoes* at http://www.wcc-coe.org/wcc/what/jpc/trade.html (Accessed 13/11/02)

[9] Collins, Maurice H., *International Transfer Pricing in the Ethical Pharmaceutical Industry* (IBFD Publication BV, 1993), p22

[10] Collins, Maurice H., *Op. Cit.*, p22

[11] *Id.*

[12] *Ibid.*, p20

[13] Article 8 (1) of TRIPS

[14] Article 31 of TRIPS

[15] The TRIPS Agreement, *Preamble*, para 6

[16] The World Health Organization (WHO), *Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines* (2001), p15

there are insufficient manufacturing capacities in the pharmaceutical sector in most DLDCs or there is no domestic manufacturer in these countries capable of handling a compulsory licensing granted by the Article,[17] the flexibility of the use of patents without authorization in the Article is ineffective.

Further, globalisation increases income and wealth in areas with high capital ownership while impoverishing societies with little capital.[18] Every so often economic development grows faster than the policy or laws drawn up by government. This economic pressure with its interest in profit can override the interest of fairness,[19] which is the concern of policy-making.[20]

The economic and political condition of DLDCs means they are treated unequally by TRIPS. The economic differences between developed and DLDCs places pressure on DLDCs. Political pressure comes from developed countries, which pharmaceutical companies are mostly based in. Though TRIPS allows the Members to exclude pharmaceuticals from patentability inventions,[21] this pressure prevents DLDCs from regulating what is legal under TRIPS.

A solution to the problem of fairness in TRIPS competition policy is beyond DLDCs capacity. So long as their economic and political situations are unsteady, they will be unable to compete with developed countries as the patent system works against them developing their own industries. France, Germany, Japan, Switzerland, Italy and Sweden introduced patents only after development of their own industry.[22] Before TRIPS, some developing countries such as India, Brazil, and Mexico tried to develop industry by acquiring basic technology through reverse engineering, and then patenting products. However, TRIPS will automatically prevent such development and the growing pharmaceutical industry in developing countries is likely to collapse.

Therefore, some changes in TRIPS provisions, clearer interpretation of TRIPS, supportive legal technical assistance, and technical cooperation,[23] which includes policy analysis and development from WTO, governments (developed countries), are urgently needed. It is essential to make changes to balance values of fairness and efficiency[24] in IPR protection of TRIPS.

III. The Doha Declaration on the TRIPS Agreement and Public Health

Since the Ministerial Conference of WTO adopted the Declaration on the TRIPS Agreement and Public Health on 14 November 2001 in Doha (Doha Declaration), there is a greater chance of fairness in TRIPS for DLDCs. The declaration addressed a number of significant points concentrating on the public health problems in DLDCs and the need to postpone implementation of TRIPS in those countries to facilitate flexibility of TRIPS on access to medicine.

Since the majority of WTO Members are developing countries, the WTO has received

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[17] The European Communities, *Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WTO, IP/C/W/339, 4 March 2002), para 5

[18] Mehmet, Ozay, Mendes, Errol, and Sinding, Robert, *Towards a Fair Global Labour Market: Avoiding a New Slave Trade* (Routledge, 1999), p19

[19] Zajac, Edward E., *Political Economy of Fairness* (The MIT Press Cambridge, Massachusetts, 1995), p5

[20] *Ibid.*, p79-81

[21] Article 27 (2) of TRIPS

[22] Ombaka, Eva, *Loc. Cit.*

[23] The WTO, *Ministerial Declaration* (Adopted 14 November 2001), p4

[24] Mehmet, Ozay, Mendes, Errol, and Sinding, Robert, *Op. Cit.*, p124

pressure to accommodate the interests of these countries,[25] mainly the elevation of economic development and the alleviation of poverty.[26] The Members have a crucial commitment to create assurance on both access to medicine and existence of R&D to invent new medicines.

Regarding these obligations, on 27 June 2002, the TRIPS Council decided an extension of the transition period for least-developed country Members to disregard patents with respect to pharmaceuticals provided under Article 66 paragraph 1 of TRIPS.[27] The least-developed country Members will not be obliged, with respect to pharmaceuticals, to apply Sections 5 and 7 of Part II of TRIPS or to enforce rights provided for under these Sections, until 1 January 2016.[28] A waiver for these countries was decided under Article 70 paragraph 9 of TRIPS.[29] In other words, they do not have to give patent protection for pharmaceuticals until 2016.

Nevertheless, there are unsolved problems on interpreting TRIPS, for example in how to determine whether DLDCs have insufficient manufacturing capacities in pharmaceuticals, how to make compulsory licensing effective in practice, and how to manage assistance and monitor these implementations. Essentially, if these problems can be resolved, optimistically the fairness of TRIPS for DLDCs might become a reality.

The declaration was responding to a proposal by a group of developing countries[30] and a group of developed countries[31] on 1 September 2001. In these drafts, both groups recognised some problems concerning access to medicine. The group of developing countries focused on the issue that 'nothing in TRIPS shall prevent Members from taking measures to protect public health'.[32] They argued that by signing TRIPS these countries did not sign their rights away to maintain public health in their countries. It is still their right to make certain policy that might conflict with TRIPS in order to provide affordable medicines. Further, the group of developed countries attempted to find a solution to the problem faced by DLDCs and agreed with the DLDCs to use the system within TRIPS to overcome the problem.

The Doha Declaration has not been implemented in practice. This paper will analyse the two proposals issued by the U.S. and the E.C. separately, regarding solutions to the problem met by international organizations in assisting DLDCs. Regarding compulsory licensing and parallel importing, neither proposal is adequate and for reasons of practicality it might be possible to take up from each proposal to provide greater fairness and to overcome problems faced by DLDCs to access medicines. The Doha Ministerial sets

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[25] Gerhart, Peter M., 'Reflections on the WTO Doha Ministerial: Slow Transformations: the WTO as a Distributive Organization', *American University International Law Review* (2002), 17, 1045, p1

[26] The WTO, *Ministerial Declaration*, (adopted on 14 November 2001), p1

[27] The WTO, *Decision of the Council for TRIPS of 27 June 2002*

[28] *Id.*

[29] "Where a product is the subject of a patent application in a Member in accordance with paragraph 8 (a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member."

[30] The member of the group are the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela

[31] The member of the group are Australia, Canada, Japan, Switzerland, and U.S

[32] The WTO, *Members Discuss Drafts for Ministerial Declaration* (21 September 2001)

up a deadline the end of 2002 for proposal relating to the declaration.

IV. Analysis of Proposal Regarding Compulsory Licensing and Parallel Importing

1. The United States Model

a. Background Paper on IPR and Health

In the United States Trade Representative (USTR) background paper on IPR and health issued on 10 November 2001, the U.S. is aiming of flexible consensus on TRIPS. It extends the period for DLDCs to fulfil their patent obligations to the U.S. under TRIPS until 2016. It proposes five year suspension of obligations for sub-Saharan African developing countries that are facing a problem with HIV/AIDS and other health crises.[33]

The question is: does it solve the problem of implementing TRIPS? Responding to the U.S. proposal, there are certain issues that might be taken into consideration. It merely defers the DLDCs from enormous risks of legal action taken by the U.S. and other developed countries, and owners of pharmaceutical companies.[34] This extension does not deal with the root of the problem faced by DLDCs in enforcing TRIPS. However, the extension is useful because it gives more time to DLDCs to set strategies to manage their weaknesses to enforce an IPR regime under TRIPS. Thus, until this date, DLDCs might legally manufacture generic (not produce under a patent) pharmaceuticals,[35] and export them to countries which are Members, where these drugs are not patented or to Members which have issued a compulsory licence for certain pharmaceuticals.

The U.S. paper also recognizes an obligation of developed countries to give incentives for its private sector and institutions to promote and encourage technology transfer to DLDCs.[36] It has not been enforced in practice since TRIPS was established. To guarantee enforcement, it is urgent for the Doha Ministerial to create a monitoring mechanism and to implement the obligation, to assist DLDCs in the transfer of new technologies from developed countries.

b. Proposal for Emergency Compulsory Drug Licensing

On 24 June 2002, the U.S. proposed a way to make effective Article 31 of TRIPS on compulsory licensing.[37] It offers the use of compulsory licensing for domestic pharmaceutical suppliers during a health crisis on condition that the products are used only in the domestic market.[38] The purpose of this proposal is to strengthen the performance of compulsory licensing and parallel importing practices. Therefore, with regards to compulsory licensing, a government may give permission to a third party to provide a patented product without consent from a

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[33] Symposium: Global Intellectual Property Rights: Boundaries of Access and Enforcement, Panel 1: AIDS Drugs and Developing World: the Role of Patents in the Access of Medicines, *Fordham Intellectual Property, Media, & Entertainment Law Journal* (2002), 12, 67, p12

[34] In spite of this, the delay, which also affirmed by the Council for TRIPS (the TRIPS Council) in the WTO, has brought optimism to developing and least-developed countries to prepare itself to implement TRIPS

[35] Nielsen, Jane, 'Pharmaceutical Patents and Developing Countries: the Conundrum of Access and Incentive', *Australian Intellectual Property Journal* (2002), 13, p40

[36] Article 66 para 2 of TRIPS

[37] The USTR, *U.S. Announces Framework to Increase Access to Drugs to Fight HIV/AIDS and other Public Health Crises* (24 June 2002), p1

[38] http://usinfo.state.gov/topical/econ/wto/02062403.htm (Accessed on 28/10/02)

patent holder. In parallel importing, an authorized patented product may be imported into a country without permission of the patent holder.

DLDCs meet both capital and cultural barriers in their efforts to force TRIPS in general to ease restrictions on the manufacture of pharmaceuticals. The countries have limited funds because of a serial economic crisis that has lasted for the past five years.[39] Moreover, the cultural problem appears when in fact, IPR has not been yet recognised broadly within the countries as important as other basic needs such as food, shelter, clothing, health care, and education.

Another problem in implementing compulsory licensing arises. A court order in a particular country is required to approve the license. The approval is needed to decide the time period of compulsory licensing.[40] This can lead to a problem of differences of legal system and a court jurisdiction. There should be an understanding and cooperation between the WTO and the judiciary authority among countries.

Another issue regarding the proposal is that the U.S. might apply the proposed compulsory licensing as a measurement to remedy anti-competitive practice.[41] This practice can prevent patent owner and other holders of IPR from abusing IPR, unreasonably restraining trade, or hampering the international transfer of technology[42] (in antitrust case[43]).

2. The European Communities Model

The E.C. issued a paper responding to the Doha Declaration on the TRIPS Agreement and Public Health on 1 March 2002. The paper focuses on the problem of making effective use of compulsory licensing while there is no domestic manufacture in DLDCs.[44]

In regards to a compulsory licence, the paper argues that DLDCs cannot grant compulsory licensing to a foreign manufacturer, because patents laws in two countries are independent of each other. However, DLDCs might grant the licence to import a patented product from other countries. But, there is no guarantee that sufficient supply will be accessible.

Under Articles 31 to 31 (f) of TRIPS a compulsory licence should be made only for the supply of a domestic market. From the patents perspective, problem would be more complicated if there is insufficient patent protection for pharmaceuticals in DLDCs. According to the E.C. paper, Article 31 (f) merely gives flexibility to DLDCs and it needs to be amended.

Article 30 of TRIPS regulates exceptions to the supply of products by compulsory licence. However, precising what is excepted is unclear. There is unclear meaning of exception in this article. It should be made clearer and a careful interpretation presented. This is important in order to create limited

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[39] Lovett, William A., 'Reflections on the WTO Doha Ministerial: Bargaining Challenges and Conflicting Interests: Implementing the Doha Round', *American University International Law Review* (2002), 17, 951, p2-8.

[40] The Department of Foreign Affairs & Trade (DFAT) Australia, *The Implementation of TRIPS in Australia* (2000), p9

[41] Kripapuri, Dora, 'Reasoned Compulsory Licensing: Applying U.S. Antitrust's "Rule of Reason" to TRIPS Compulsory Licensing Provision', *New England Law Review* (2002), 36, 669, p16

[42] The WTO, *TRIPS and Pharmaceuticals Patents* (April 2001)

[43] The WTO Pharmaceutical Patent Dispute between the U.S. and India, 17 Wis. Int'l L.J. 579, 600 (1999)

[44] The European Communities, *Op. Cit.*, para 3

exception only for certain countries, which are facing public health crises. Failure to clarify exceptions could undermine industry supports on pharmaceuticals and could damage protection of IPR system as a whole arranged by TRIPS.

Notably, the E.C. paper goes beyond the U.S. proposal in anticipating procedural difficulties in the TRIPS Council. It highlights the importance of TRIPS interpretation,[45] and proposes amendments to certain articles in TRIPS that require full compliance with other relevant provision of TRIPS in order to avoid inconsistency on TRIPS procedure.

V. Analysis of the Model Implementation and Possible Problem Solving of Creating Greater Fairness of TRIPS for DLDCs

Some DLDCs are recognised as agricultural countries or natural resources-based countries. They are very different to developed countries that are industrial-based countries or further, 'knowledge-based'[46] countries. This gap becomes a problem in balancing the needs between the two distinct natures of the countries.

TRIPS might create its own system for overcoming the problems of implementation. In other words, there should be problem-solving arrangement in TRIPS that is able to resolve the problems particularly with respect to its enforcement on DLDCs. By making compulsory licensing and parallel importing effective and by creating monitoring measures of its practice, TRIPS can help countries to get affordable medicine.[47] By allowing parallel importing, it might prevent 'piracy' of patented pharmaceuticals,[48] while the patent holder is enabled to control their product distribution. However, some articles of TRIPS should be changed to take into account recent conditions of DLDCs.

To begin with, quality of life is still insufficient and it is necessary to improve it in DLDCs. Next, in the area of manufacture it is necessary to make an agreement to develop 'manufacturing capacity'[49] of pharmaceuticals in a country.[50] When compulsory licensing and parallel importing are allowed for particular conditions in a country, a manufactures will be able to provide medicines to the signatory countries of an agreement. This is one way to solve the problem of a deficiency of a pharmaceutical manufacturing facility in a country.[51]

Other solutions include balancing the protection of intellectual property, which serves the needs of the IPR holder,[52] with the need for affordable-priced drugs for DLDCs. This problem might be solved by using the patents principle that requires full disclosure[53] of one invention to the public, and enable other people to study the invention.

Furthermore, developed countries might give incentive for R&D into of diseases and

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[45] *Ibid.*, para 29 (See Articles 30 and 27 para 1 of TRIPS)

[46] The WIPO, *Vision and Strategic Direction of WIPO* (Endorsed in Geneva 20-29 September 1999)

[47] Rothnie, Warwick, *Parallel Imports* (Sweet & Maxwell, 1993), p471-3

[48] Revesz, John, 'Trade Related Aspects of Intellectual Property Rights' in *Industrial and Intellectual Property Materials* (Faculty of Law, University of New South Wales, 2000), p31

[49] The DFAT Australia, 'TRIPS and Public Health', *TRIPS Update* (5 April 2002)

[50] The WTO, *Technical Assistance and Capacity Building* (8 October 2002)

[51] The Zanzibar Declaration, *Integrated Framework for Trade Related Technical Assistance to Least-Developed Countries* 24 July 2001 in The WTO, *Ministerial Declaration* (Adopted on 14 November 2001), p7

[52] Bifani, Paolo, 'The New Mercantilism and the International Appropriation of Technology', *Technology, Trade Policy and the Uruguay Round - Papers and Proceedings of a Round Table* (1989) p149-50

[53] Loughlan, Patricia, *Intellectual Property: Creative and Marketing Rights* (LBC Information Services, 1998), p141

technology transfer to DLDCs. Finally, it is important to create harmonization of differences among countries. Harmonization means 'the coordination of economic policy actions and measures in order to lessen international differences in such actions',[54] not necessarily uniformity of system. Such harmonization will lead to greater democracy, justice, and fairness in international law.[55] In this case, understanding and awareness[56] are needed to create harmonization in international scope.

VI. Recommendations

Based on the above the analysis, several recommendations can be made with the purpose of creating greater fairness in TRIPS implementation:

- The Doha Ministers should adopt the U.S. model for easing TRIPS in its relation to DLDCs and should adopt the E.C. model in its proposal concerning amendment of Article 31 (f) of TRIPS to make TRIPS effectively useful for DLDCs;
- The developed countries should adopt the U.S. model and apply the minimum standard only that TRIPS recommends in situation where DLDCs have a health crisis;
- The TRIPS Council should provide clarity of interpretation of TRIPS57 in a way that supports public health, eases access to medicines, and gives incentives to R&D interested in new medicines,[58] by providing uniform interpretations especially to determine the exceptions provided by Article 30 of TRIPS. It is important also to ensure that exceptions only apply to countries, which have public health crises. The safeguards are sufficient to protect the rights of the patent holder from irrelevant conduct or unfair commercial use[59] of patents related to public health crises;
- The WTO should manage more effectively the peaceful IPR dispute settlement system on pharmaceuticals patent;[60]
- International organizations: the WTO and the World Intellectual Property Rights (WIPO), should optimise coordination between them in regards to promoting protection of IPR in Members countries and to give supporting assistance to DLDCs to put TRIPS into practice;[61] and
- A study should be conducted by the World Health Organization (WHO)[62] on policy-making related to international trade and public health.

VII. Conclusion

From the perspective of DLDCs, TRIPS, which set up the principles of IPR, is unfair.[63] It

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[54] Hansson, Gote, *Harmonization and International Trade* (Routledge, 1990), p1

[55] Franck, Thomas M., *Fairness in International Law and Institutions* (Clarendon Press, Oxford, 1995), p137

[56] *Ibid.*, p7-10

[57] Ford, Sara M., 'Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents', *American University International Law Review* (2000), 15, 941, p5

[58] The WTO, *Ministerial Declaration* (Adopted on 14 November 2001), p3

[59] Correa, Carlos Maria, 'Public Health and International Law: Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals', *Chicago Journal of International Law* (2002), 3,69, p10

[60] Yu, Peter K., 'Toward A Nonzero-Sum Approach to Resolving Global Intellectual Property Disputes: What We can Learn from Mediators, Business Strategists, and International Relations Theorists', *University of Cincinnati Law Review* (2002), 70, 569, *p19*-21

[61] *The Agreement between the WIPO and the WTO* (Done in Geneva, 22 December 1995)

[62] The WTO, *WTO Agreement and Public Health* (20 August 2002)

[63] Raggett, Tom, *GATT and Patent Reform: the Global Strengthening of Patent Protection and the Implications for the Pharmaceuticals Industry* (Financial Times, Management Reports, Pharmaceuticals and Healthcare Publishing, 1996), p126

seems that international trade practice brings advantages to the world as a whole, but not automatically provide equal benefit to each country involved in the practice (especially DLDCs).[64] TRIPS protects the rights of produces of intellectual property, but many DLDCs are not in a position to engage with R&D to produce new inventions.[65] Therefore they cannot benefit from these provisions, and in fact, the provisions works against DLDCs developing a domestic industry.

It is not solely IPR that discriminates against DLDCs. Several provisions on TRIPS are unsuitable for condition in these countries resulting in TRIPS being ineffective. If TRIPS is enforced without the amendment of Article 31 (f), it becomes inequitable for DLDCs. It is a challenge for WTO to gather all possible solutions by the end of 2002. However, this attempt to find a solution is very difficult.

In summary, regarding these facts, it is important for countries and WTO to create greater fairness in TRIPS. Delaying the implementation of TRIPS for DLDCs is only temporary. TRIPS should not adopt arguments that could be used by a powerful party to protect corporate profit regardless of the cost in human life. Therefore, appropriate approaches and mechanisms with the purpose of the fulfilling the basic purpose of patents, which is to ensure society, continue making innovation in technology;[66] and with the purpose of ensuring fairness of IPR implementation in international trade practices, should be formulated.

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